

US EPA ARCHIVE DOCUMENT



EPA's Pesticide Program

FY 2005 Annual Report

Message from the Director

EPA's Pesticide Program is proudly dedicated to fulfilling its mission to protect public health and the environment by ensuring that pesticides and alternatives are safe and available. We also must ensure that pesticides are regulated fairly and efficiently. In FY 2005, OPP made significant progress in carrying out these important responsibilities through the efforts of many talented and hard-working employees within the Pesticide Program, and through our partners in the EPA regional offices and state and tribal pesticide regulatory agencies.

Beginning with our registration program, where OPP stands at the gateway to a multi-billion dollar pesticide market, we had a productive year. Twenty-two (22) new active ingredients were registered – 2 antimicrobials, 12 biopesticides, and 8 conventionals, 2 of which are associated with reduced-risk uses. We also added 164 new uses to existing active ingredients. Significantly, over 99 percent of our Pesticide Registration Improvement Act (PRIA) deadlines were met for all categories. In so doing, for the first time in the Pesticide Program's history, we have virtually eliminated backlogs in our registration program.

Turning to our accomplishments in reregistration and tolerance reassessment, we also made good progress. We reassessed 724 tolerances, including 168 reassessments of inert ingredients -- the largest number of inert reassessments in one year in our program's history. This leaves us with 1,904 tolerances to reassess by August 3, 2006. In addition, we completed 28 reregistration eligibility decisions (REDs) and 13 tolerance reassessment decisions (TREDs) in FY 2005. Beyond the numerical accomplishments are the public health and environmental protections they represent. These actions and many others that are being carried out through RED follow-up will result in meaningful label changes to protect workers, children, the environment, and the general public. Clearly, the task before us to meet our tolerance reassessment and reregistration commitments remains, but I am confident in our ability to meet the challenge.

While it would be difficult to list every accomplishment throughout OPP this past year, I want to note a few that reflect a significant amount of effort by many throughout the program. First, we continued to meet all of our court-ordered endangered species deadlines, while building the internal infrastructure to make endangered species review part of our everyday business. We also negotiated a voluntary cancellation of two products that were the cause of a large number of cat incidents. To enhance worker protection, we finalized the national worker protection program assessment and initiated pilots for hazard communication. Work in 2005 also provided a solid science-based foundation for the U.S. nominations for Critical Use Exemptions for Methyl Bromide under the Montreal Protocol.

Of course, underlying all of our regulatory work is science. I am proud that the Pesticide Program continues to be a leader in EPA and the world in the quality of its science. That was evidenced at a Science Advisory Board meeting last September regarding our hazard assessment for organic arsenic. Another example was our carbamate cumulative assessment which was praised by the FIFRA Scientific Advisory Panel.

Successfully developing a solid regulatory foundation that reflects current practice and realities is critically important. In FY 2005, OPP had a very impressive year laying the groundwork for a solid regulatory foundation for the future. We proposed rules for: (1) Part 158, the data requirements for registering conventional pesticides; (2) Registration Review, the successor program to reregistration, to establish a plan for the Pesticide Program to review older chemicals on a 15-year cycle; (3) Container design and containment, to protect the public and users from contamination associated with poor container design and a lack of proper containment at distribution sites; (4) Section 18 revisions, to reduce

the burden on states and EPA without sacrificing public health or environmental protection; and (5) Human testing, to ensure volunteers for human tests are treated fairly and ethically if they choose to participate in such a study. While some of these are already finalized, I am hopeful that we will complete most if not all of these rules in FY 2006, which will strengthen the regulatory foundation of the Program for many years to come.

FY 2005 also saw the Pesticide Program kick into high gear in our efforts to enhance our information management, which will ultimately allow us to do our work more efficiently and effectively, thus increasing the speed with which we achieve our goals and vision. PRIA tracking has been indispensable in managing our PRIA commitments. We've begun investing in electronic submission, electronic jackets, and an electronic document management system.

Finally, I want to acknowledge that 2005 was the year that the Pesticide Program invested heavily in developing results indicators. Not only is it important for us to complete our registration and reregistration commitments, but we must also find more effective ways to communicate the environmental, human health, and economic outcomes of all that work. In 2005, the Program began identifying indicators and measures that will, in time, allow us to more effectively describe those outcomes. I'm confident that our work in this area will pay off.

I hope you will join me in reviewing our Annual Report for FY 2005 and that you will gain a greater understanding of the depth and breadth of work accomplished throughout the Pesticide Program during the past year. We've accomplished much, yet there is much to do. We look forward to meeting the challenges ahead as reflected in our vision for the future: "protecting public health and the environment by ensuring pesticides and alternatives are safe and available for a healthy America."

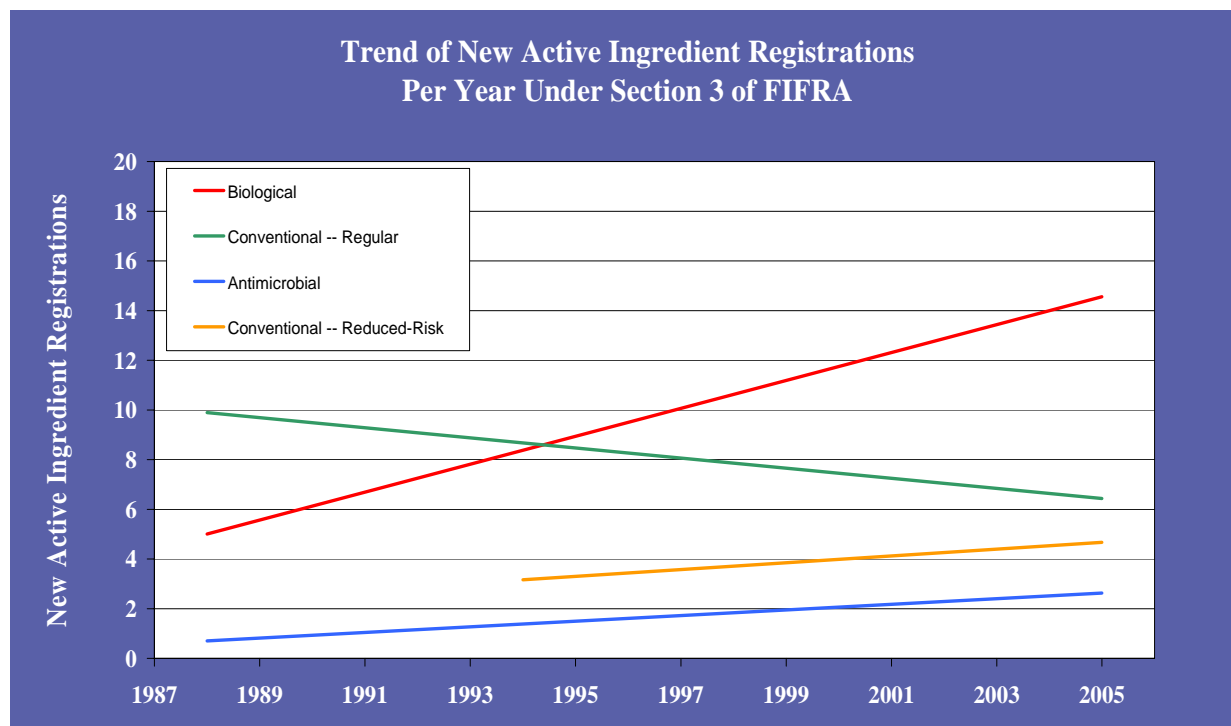
James J. Jones, Director
Office of Pesticide Programs

EPA's Pesticide Program in Action

Just the Facts

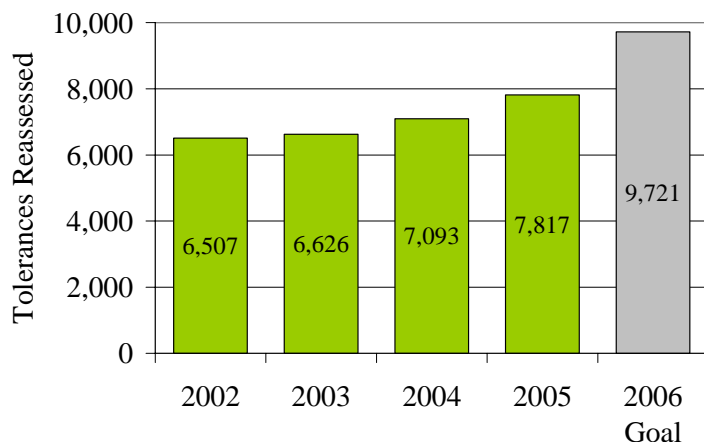
FY 2005 Pesticide Program Budget	\$140.7 million	
Program Administration and Implementation (Payroll and administrative expenses for HQ and Regions)	\$84.4 million	60.0%
Grants and Contracts (For HQ and Regions)	\$43.8 million	31.2%
Other (Lab expenses and support activities for HQ and Regions)	\$12.4 million	8.8%
Reregistration Eligibility Decisions Completed in FY 2005	28	
Reregistration Eligibility Decisions Completed through FY 2005	271	
IREDs and Tolerance Reassessment Eligibility Decisions	13	
Tolerance Reassessments Completed in FY 2005	724	
Tolerances Reassessed Through FY 2005	7,817	(1,904 remaining)
New Active Ingredient Registrations	22	
Biological	12	54.5 %
Conventional - Reduced Risk	2	9.1 %
Conventional	6	27.3 %
Antimicrobial	2	9.1 %

This graph indicates the long-term trend of active ingredient registrations toward safer chemistries and use patterns. The number of new biological and antimicrobial active ingredient registrations has tended to increase annually, while during the same period new conventional active ingredient registrations have been decreasing. The number of new reduced-risk conventional pesticides has increased each year since that category of pesticide was first introduced in 1994.



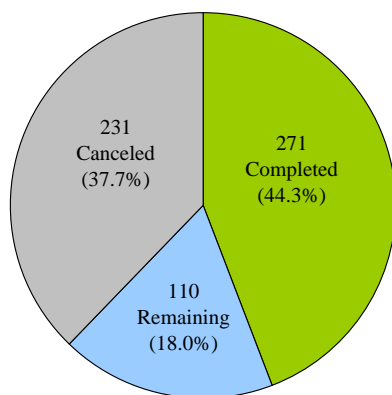
EPA is required to reassess 9,721 maximum allowable pesticide residue limits, called tolerances, by August 2006. This graph indicates annual progress toward that goal as of FY 2005, 7,817 of a total 9,721 tolerances have been reassessed.

Overall Status of Tolerance Reassessments



EPA is reviewing older pesticides (those initially registered before November 1984) under the Federal Insecticide, Fungicide, and Rodenticide Act to ensure that they meet current scientific and regulatory standards. This process, called reregistration, considers the human health and ecological effects of pesticides and results in actions to reduce risks that are of concern. After reviewing extensive scientific data on pesticides undergoing reregistration, the Agency issues Reregistration Eligibility Decisions (REDs) that explain the rationale for its decisions and the conditions under which older pesticides can continue to be available in the marketplace. As of FY 2005, over 80% of reregistration eligibility cases have been decided.

Overall Status of REDs



Biotechnology

Products of biotechnology play a key role in reducing both the use of pesticides and exposure to pesticide residues. In FY 2005, EPA's Pesticide Program continued to register and grant experimental use permits for products of biotechnology, such as [plant-incorporated protectants](#), while at the same time taking action to ensure their safety and manage the potential for insects to develop resistance. Products of biotechnology undergo rigorous scientific review and public comment, and major products receive independent peer reviews held at public meetings. EPA also coordinates its biotechnology regulatory activities with other government offices, stakeholders, and the international community.

Regulating the Products of Biotechnology

Bt Corn Product Offers Protection Against Corn Rootworm - In FY 2005, the Pesticide Program approved the use of a new corn plant-incorporated protectant (PIP) designed to control corn rootworm, a widespread and destructive insect pest responsible for the single largest use of conventional insecticides in the United States. The new product, Event DAS-59122-7 Corn, produces its own insecticide within the corn plant derived from [Bacillus thuringiensis \(Bt\)](#), a naturally occurring soil bacterium. This is the second PIP to offer protection against corn rootworm and is expected to result in a further reduction of chemical insecticide use by growers. This reduction in use will benefit the environment directly and should mean less chemical exposure to people who apply pesticides to corn.

Label Amendments Provide Cotton Growers Protection Against Cabbage Looper Infestation - In FY 2005, record numbers of cabbage looper eggs in pre-squaring cotton refuge fields were reported to the Pesticide Program by the Louisiana State University Cooperative Extension Service. Pre-squaring cotton is not considered to be a host for either tobacco budworm or cotton bollworm, but if the refuge is not properly managed at the pre-squaring stage, it will not be an effective refuge for susceptible tobacco budworm and cotton bollworm that feed on the squares, blooms, and bolls later in the season. The State of Louisiana was prepared to call for a crisis exemption under Section 18, but by working with registrants for three products, the Pesticide Program approved label amendments for three registered Bt cotton products (Bollgard, Bollgard II, and WideStrike) to allow for pre-square treatment of various leaf-eating species (including cabbage looper) in non-Bt cotton refuges. Prior to this action, no such insecticide applications were permitted in the refuge.

Experimental Use Permits - Six PIP Experimental Use Permits (EUPs), either extensions or amendments to active ingredients already under field trial or new active ingredients, were issued in FY 2005. These experimental Bt products for corn, cotton, and tomatoes indicate a potential for reducing the use of conventional chemical pesticides currently used for these crops. A list of [currently active PIP EUPs](#) is available on the Pesticide Program's Web page.

Insect Resistance Management - The potential for insects to develop resistance to the Bt protein poses a threat to the future use of Bt PIPs. Therefore, the Pesticide Program has imposed management requirements on PIPs to reduce the likelihood that pests will develop resistance to Bt proteins. In FY 2005, for Event DAS-59122-7 Corn, the Program required that buffer zones within the total crop acreage be planted with non-Bt corn to serve as a "refuge." The insect populations in the refuges will help prevent resistance development when they cross-breed with insects in the Bt fields. This resistance management strategy was developed as part of the conditional, five-year registration of Event DAS-59122-7 Corn, and EPA will require routine monitoring and documentation that these measures are followed.

Ensuring the Safety of Products and the Food Supply

PIP Analytical Method Validation Program - Because PIP plants in the field cannot be distinguished visually from conventional plants, current PIP registration guidelines require registrants to submit methods for the detection of unique PIP DNA sequences, as well as methods to detect the proteins expressed by those DNA sequences. In FY 2005, the Pesticide Program reviewed data from the first PIP method validation, which used a lateral-flow test strip system to detect the presence of Cry1Ab (an insecticidal protein) in corn seed. Validation of Enzyme Linked Immunosorbent Assays (ELISAs) for the detection of other Bt Cry proteins in corn and cotton seed is also under way. These efforts allow EPA to comply with Food and Drug Administration (FDA) testing requirements for registered PIPs in food commodities, thereby ensuring the safety of the U.S. food supply.

Bt10 Investigation and Enforcement - In FY 2005, EPA investigated reports of the unauthorized release of small quantities of Bt10, a PIP that produces the Cry1Ab protein. Although Bt10 is unregistered, EPA has registered Bt11, a very similar product that also produces Cry1Ab, and has authorized the Cry1Ab protein in food and feed under an exemption from the requirement of a tolerance. The release of Bt10 is not expected to pose risks to either human health or the environment. In cooperation with the U.S. Department of Agriculture's Animal and Plant Health Inspection Service, the Food and Drug Administration, and the Bt10 producer, EPA is working to take appropriate enforcement action and ensure that Bt10 does not inadvertently affect the food and feed supply. Additional information about [Bt10](#) is available on EPA's Web site.

Working with Partners to Provide Information

U.S. Regulatory Agencies Unified Biotechnology Web Site - In FY 2005, EPA continued to work with other federal agencies to provide the public with information about agricultural biotechnology products in the United States through a searchable Internet database. The database covers all genetically engineered crop plants intended for food or feed that have completed the recommended or required reviews for food, feed, or planting use in the United States, and provides a one-stop access point to information on products of biotechnology and their regulatory states. This effort also serves to further the understanding of the United States' oversight system for products of biotechnology, as well as to ensure that new biotechnology products are safe for public health and the environment. The Web site and database are available at: <http://usbiotechreg.nbio.gov>.

North American Biotechnology Initiative - In FY 2005, EPA continued to improve communications and regulatory coordination among biotechnology officials in Canada, Mexico, and the United States. Through the initiative, EPA has also developed programs of technical assistance for Mexico and Central and South American countries.

Codex Task Force on Foods Derived from Biotechnology - EPA participates in the Codex Task Force on Foods Derived from Biotechnology and bilateral information exchange and projects with Japan, China, and other countries. In FY 2005, two workshops were held in China and two in the United States as part of an effort to better understand the science and regulatory processes in each country.

Information Exchange - As part of the effort to promote information exchange, the Pesticide Program hosts a steady stream of international visitors requesting briefings and other information on EPA's regulation of pesticides. In FY 2005, the Program had a total of 216 visitors from 49 countries, with the majority of visitor groups requesting meetings to discuss issues including biotechnology, biopesticides registration, pollution prevention, and food safety. EPA scientists also serve as instructors in a biotechnology course sponsored by USDA's Foreign Agricultural Service.

Endangered Species Protection

In accordance with the [Endangered Species Act](#), EPA's Pesticide Program has conducted screening-level endangered species assessments in its overall pesticide risk assessments for many years. In FY 2005, the Pesticide Program made major investments to ensure that its program will adequately protect threatened and endangered species and their critical habitat, while at the same time minimizing the impact on agriculture and other pesticide users. Improvements to the [Endangered Species Protection Program](#) include upgrades to the scientific methods for endangered species risk assessments and the routine incorporation of these assessments into registration, reregistration, and for the future, registration review decisions. The Program continued improving cooperative efforts with the U.S. Fish and Wildlife Service (FWS) and the National Marine Fisheries Service (NMFS), jointly referred to as the Services, to effectively implement the process for consultation between EPA and the Services.

Program Improvements

Endangered Species Protection Program - In FY 2005, the Pesticide Program worked to finalize its approach to field implementation of the Agency's [Endangered Species Protection Program \(ESPP\)](#). The goal of the ESPP is to carry out responsibilities under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) in compliance with the Endangered Species Act (ESA), while at the same time not placing unnecessary burden on the agriculture community and other pesticide users. EPA will implement its program through pesticide label statements referring users to Endangered Species Protection Bulletins, as appropriate, that will contain geographically specific pesticide use limitations when such limitations are necessary to protect federally listed species or their designated critical habitat from potential harm due to pesticide use.

Endangered Species Analyses in the Section 18 Program - Because emergency exemption ([Section 18](#)) requests are time critical, EPA worked in FY 2005 to develop an approach for endangered species assessment and consultation in emergency situations. Under this approach, states, tribes and federal agencies will be expected to demonstrate that they have made a credible effort to identify and address endangered species issues in their emergency exemption requests. Such efforts by Section 18 applicants will make it more likely that the Pesticide Program will be able to conduct its endangered species assessment and consult with the Services, as necessary, within the time constraints for review of Section 18 applications. Under [Counterpart Regulations](#) issued by the Services in 2004, emergencies under Section 18 may also be treated as emergencies for purposes of the ESA consultation requirements. As a result, if EPA cannot perform a comprehensive endangered species assessment or, if applicable, initiate and complete consultation within the time constraints for review of a Section 18 application, EPA may complete any necessary consultation as soon as practicable after the emergency. These efforts provide the opportunity to balance the need to address emergencies with the responsibility to protect threatened and endangered species.

Risk Assessment and Mitigation

Conducting Endangered Species Risk Assessments - As part of its efforts to improve protection for listed species, EPA is working to routinely include endangered and threatened species risk assessments in its registration and reregistration decisions. While the Pesticide Program does not anticipate that this work will be fully integrated into the registration and reregistration processes until 2007, the Program has already begun the integration process by initiating consultation with the Services and requesting that a Service representative work side by side with EPA ecological risk assessors on [aldicarb](#), [carbofuran](#), and a suite of nine pesticides registered to control rodents. Partnering with the Services in this manner, under the new procedures outlined in the [Counterpart Regulations](#) and [Alternative Consultation Agreement](#), is expected to result in effective and timely conclusions about whether these pesticides are likely to have effects on listed plant or animal species or their critical habitat.

Settlement Agreement Regarding Endangered Species - In FY 2005, EPA and the Department of Justice signed a [Settlement Agreement](#) that resolves a lawsuit brought against the Agency by the Center for Biological Diversity and the Save Our Springs Alliance. The Agreement establishes a series of deadlines for the Agency to make “effects determinations” for pesticides containing any of six active ingredients (atrazine, diazinon, carbaryl, prometon, metolachlor, and simazine), to determine whether they may have potential effects on the Barton Springs salamander, *Eurycea sosorum*, or its designated critical habitat. Under the Agreement, if EPA determines that an action “may affect and is likely to adversely affect” the salamander or its designated critical habitat, the Agency will initiate formal consultation with FWS. The Agreement also states that plaintiffs in this case will not seek further use restrictions for these pesticides during EPA’s review of potential effects. If EPA determines a pesticide may affect the Barton Springs salamander, plaintiffs may seek further use restrictions through a separate legal action. EPA provided a 15-day comment period on the proposed Agreement and considered the comments received prior to signing. [Additional information](#) is available on the Pesticide Program’s Web site.

Implementation of the Counterpart Regulations - In FY 2005, EPA and the Services developed and offered endangered species training to risk assessors in the Pesticide Program. This training is necessary for the Program to utilize the 2004 [Counterpart Regulations](#) and [Alternative Consultation Agreement](#). The training and resulting certification will permit certified staff to determine whether a pesticide is “not likely to adversely affect” a listed species or its designated critical habitat without further consultation with the Services. By making the process more efficient and effective, the new regulations will allow EPA and the Services to jointly focus the bulk of their resources on determining how best to manage the use of pesticides that may pose a more significant threat to listed species. This will improve protection for endangered and threatened species.

Public Awareness and Involvement

Endangered Species Protection Bulletins - As part of an ongoing Interagency Agreement with the U.S. Geological Survey, the Pesticide Program has been working to improve endangered species protection through upgraded Endangered Species Protection Bulletins. The new Bulletins, once issued, will be more readable, user friendly, and visually appealing. The design and mapping process has been upgraded to take advantage of Geographic Information System technology and to automate many aspects of Bulletin development, thus making the development process more efficient and reliable. In FY 2005, the Program continued work on the development of Bulletins Live!, a new Web-based system that will allow users to review and print Bulletins from the Internet. Information from Bulletins will also be available from EPA through a toll-free number. Bulletins Live! uses a rolling six-month update system, so that pesticide users can plan their applications up to six months in advance and be assured the requirements will not change. It also allows EPA to update Bulletins as updates are required, rather than waiting until a particular date during the year. These features provide a balance between implementing measures to protect listed species quickly once they are known, and providing agriculture and other pesticide users with some certainty when planning their pesticide applications. The Bulletins, which will become enforceable pesticide use requirements, will contain detailed maps of geographic areas in which pesticide use may be limited, the manner in which pesticides should be used to ensure protection, and educational information about the species being protected.

Public Outreach and Public Input - To ensure public awareness and involvement in its efforts to protect listed species, the Pesticide Program in early FY 2005 hosted two public workshops on its listed species risk assessment process. In developing the ESPP, EPA also presented information and relied on extensive input from the [Pesticide Program Dialogue Committee \(PPDC\)](#). The input and advice provided by stakeholders through the PPDC is viewed as critical by EPA to ensure success of this enhanced program to protect listed species from the potential effects of pesticides. In order to ensure that the user community and public are aware of how to obtain Bulletins through the new Web-based and print-on-demand systems, as well as generally aware of the implementation provisions of the ESPP, the Program also plans to hold a national public workshop in FY 2006.

Homeland Security and Emergency Response

EPA's Pesticide Program works with EPA's Office of Homeland Security, regional offices, other federal agencies, states, and the pesticide industry to meet its obligations to help protect the nation's public health, food supplies, and agriculture from potential threats of terrorism and other environmental emergencies. In FY 2005, EPA continued to strengthen its capacity to prevent, prepare for, and if necessary respond to potential threats and emergencies. The Pesticide Program worked to identify suitable pesticides for high consequence crop and livestock diseases (e.g., Asian soybean rust and avian influenza), coordinated response capabilities with other agencies, responded to public emergencies and health threats, and improved laboratory research capabilities and methods development.

Protecting Food and Agriculture

Control of Soybean Rust and Other Crop and Livestock Diseases - As part of its homeland security effort, EPA has been working with USDA, states, and the pesticide industry to identify pesticides that EPA could approve to prepare for and control pathogens of concern that might be naturally or intentionally introduced into the United States. In FYs 2004 and 2005, for example, EPA approved emergency ([Section 18](#)) exemptions for the use of several pesticides to control Asian soybean rust, which was a select agent under the Agricultural Bioterrorism Protection Act. EPA also registered additional pesticides for control of soybean rust and established tolerances (allowable residues on food). When soybean rust was found in the United States this year, all of these tools were in place for rapid use. EPA is continuing this effort for other crop and livestock diseases. Additional information about [soybean rust](#) is available on EPA's Web site.

Food Emergency Response Network - The Pesticide Program represents EPA on the [Food Emergency Response Network \(FERN\)](#) Steering Committee, which is administered by USDA and FDA and consists of 88 federal labs, state agriculture labs, and veterinary labs that analyze food for contaminants. FERN's mission is to analyze food samples in the event of a biological, chemical, or radiological attack on the food supply of the United States. In FY 2005, FERN continued to develop short- and long-term training for federal and state analysts on select agent methods. FERN is also instituting a proficiency-testing program for all areas (biological, chemical, and radiological), and has established a secure electronic communications network ([eLexnet](#)).

Emergency Preparedness and Response

Hurricane Katrina Response Efforts - In the aftermath of Hurricane Katrina, the Pesticide Program worked with EPA Headquarters, regional offices, and other federal and state agencies to provide technical and regulatory support to relief and cleanup efforts. EPA coordinated with the Department of Defense in preparation for the wide-scale aerial spraying of insecticides to control mosquitoes and flies. EPA also shared regulatory and technical information on pest control, pesticide needs, and disposal of orphaned pesticide containers. In order to facilitate the cleanup and reoccupancy of buildings, EPA provided broad guidance on disinfection, molds, and mildews. EPA activities to support the hurricane response efforts have continued into FY 2006, and include responding to inquiries concerning sulfuryl fluoride and wood treatment for termites, as well as helping to establish geographic information system (GIS) labs in affected areas.

Protection of the Public from Mosquitoes - In certain areas of the United States, mosquitoes can transmit diseases like West Nile virus and equine encephalitis, which may pose a serious risk to public health. In FY 2005, as part of the effort to combat mosquitoes and the public health hazards they present, the Pesticide Program worked with the state of California to grant a public health exemption (Section 18) for the use of phenothrin (sumithrin) + piperonyl butoxide on adult mosquitoes to control West Nile virus in treatment locations adjacent to the commercial production of almonds, pasture fields, rice, and walnuts. Although this pesticide is not registered for agricultural use, it is registered for mosquito abatement in

residential and public park areas. While community-wide mosquito abatement is necessary in residential and recreational areas, these areas are starting to be more frequently found within or adjacent to the urban-agriculture interface. EPA determined that the State of California was faced with a justified public health emergency based on the difficulties and obstacles presented by the available alternatives and the fact that this use pattern is not likely to result in any detectable residues on commercial crops. The Program also made [guidance on mosquito control](#) available through EPA's Web site.

Cleanup of an Anthrax-Contaminated Site - In July 2005, EPA's Pesticide Program worked with EPA's Office of Solid Waste and Emergency Response to issue a public health ([Section 18](#)) exemption for using bleach to decontaminate contaminated boxes in the basement of a building in Boca Raton, FL, the last site to be cleaned up after the October 2001 "anthrax attacks." Since 2001, EPA has approved 28 and rejected 35 crisis exemption requests from a total of 63 received. EPA has issued two public health exemptions as well.

Research and Methods Development

Emerging Technologies and Techniques - The Pesticide Program's Analytical Chemistry Lab is investigating the use of technology that will enable labs to quickly respond to a homeland security incident where little may be known about the agents in question and where quick analytical response and the capability to use a single analysis to screen for multiple analytes are required. Some of the methods being investigated include high pressure liquid chromatography and tandem mass spectrometry (LC/MS/MS) detection with a multimode source, and gas chromatography with mass spectrometry detection (GC/MSD) and purge and trap capability. LC/MS/MS provides state-of-the-art instrumentation with increased productivity and sensitivity. Research at the Analytical Chemistry Branch has confirmed that it is possible to analyze certain types of water samples directly by LC/MS/MS without any sample preparation, cleanup, or extraction. LC/MS/MS also allows for the analysis of compounds that are not amenable to gas chromatographic techniques. The new multimode source has the potential to make screening for pesticides more efficient, allowing for a larger number of compounds to be identified within one sample injection. The use of and GC/MSD purge and trap will support some of the methods in EPA's [Standardized Analytical Methods for Use During Homeland Security Events](#).

Efficacy Test Methods for Products to Inactivate *Bacillus anthracis* - The Pesticide Program is responsible for regulating antimicrobial products, including sporicides, used to treat and decontaminate inanimate surfaces. In response to the *Bacillus anthracis* attacks of 2001 and the associated need for verifying the performance of chemicals for building decontamination, EPA initiated research to evaluate and improve efficacy test methods for sporicidal chemicals. Using funds provided by EPA's Office of Research and Development (Safe Buildings Program), the Program established an interagency collaborative research program to conduct the evaluation of the test methods. Interagency agreements were placed with the Food and Drug Administration and the Department of Defense to provide technical assistance and laboratory resources. In September 2005, the Pesticide Program organized a symposium for the Association of Analytical Chemists (AOAC)-International Annual Meeting, which consisted of a diverse panel of experts from the federal government, industry, and contract laboratory arenas, to discuss experiences and perspectives on efficacy testing of sporicides. These efforts will improve the efficacy assessment of sporicides and will be used to develop new regulatory guidelines and performance standards, acceptable across federal agencies, for sporicidal products used in the treatment of buildings and contents contaminated with spores of *Bacillus anthracis*.

Laboratory Preparedness for Biological Incidents - The Pesticide Program's Microbiology Laboratory is registered under the Centers for Disease Control and Prevention (CDC) Select Agent Program to possess, use, or transfer *Bacillus anthracis*. The laboratory includes two Biosafety Level 3 laboratories that are appropriately configured to work with *Bacillus anthracis* and other infectious pathogens. In FY 2005, the construction of a triage area for processing samples that may contain biological and chemical agents was completed, enabling scientists to conduct analyses covered by the CDC Select Agent Program.

Surrogate Studies for Anthrax - In collaboration with EPA's Office of Research and Development and the U.S. Army's Edgewood Chemical Biological Center, the Pesticide Program's Microbiology Laboratory in FY 2005 designed and coordinated a comparative study of *Bacillus anthracis*-Ames and two potential surrogates. The purpose of the study was to generate data to support the selection of a surrogate microbe of *Bacillus anthracis* for conducting laboratory efficacy tests.

Pesticide Outreach and Education

Through outreach and education, the Pesticide Program is working in a number of arenas to help encourage safe and responsible pesticide management practices, as well as compliance with pesticide safety regulations and standards. Among the activities being carried out in agricultural and urban settings are efforts to reduce pesticide risks and exposure in vulnerable communities, and training programs to educate workers and applicators about safe pesticide use.

Providing Information to a Broader Public

Spanish-Language Outreach Campaign - In an effort to raise environmental awareness among Spanish-speaking communities about the dangers of pesticide exposure, the Pesticide Program in FY 2005 worked with television, print, and radio networks in key media markets to reach a larger portion of the Hispanic community. Outreach projects included television segments on poison prevention and exposure, radio programs and [public service announcements](#) on pesticide safety in both farming and urban communities, and newspaper articles and interviews highlighting pesticide poisoning facts and pesticide safety information for families and children. Through the combined viewership and listenership of these efforts, the Program's message reached over 3.7 million Spanish-speaking individuals.

HUD Kiosk Project - In FY 2005, the Pesticide Program worked with the U.S. Department of Housing and Urban Development (HUD) to provide information about pest control and pesticide safety through electronic government kiosks. Available free of charge at nearly 100 locations across the United States including groceries, shopping malls, and public libraries, the kiosks provide the public with information and services from EPA, as well as the Department of Education, the Department of Labor, the Internal Revenue Service, and HUD. Users are able to access and print the information in both English and Spanish. Using kiosk technology, the Pesticide Program is furthering its efforts to make pesticide information more broadly available to the public in forms that are convenient and easy to access.

Protection of Pets - The Pesticide Program places high priority on safeguarding pets from the potential risks of pesticide products to control fleas, ticks, and other animal pests. In FY 2005, the Program continued its efforts to provide the public with information about safe pet product use by launching its [Protecting Pets Web page](#). This new resource includes links to factsheets about controlling fleas and ticks on pets and identifying counterfeit pet products, as well as recent consumer alerts and regulatory actions affecting pet products.

Washington Metro and EPA Safe Pesticide Use Campaign - As part of its ongoing effort to spread its safe pesticide use messages, the Pesticide Program utilized space donated to EPA by the Washington Metropolitan Area Transit Authority (WMATA) for the purpose of displaying the [Read the Label First!](#) message. WMATA provides this free space as a public service once annually. Throughout the month of August 2005, the displays were seen on 200 randomly selected buses, including tail-light displays on 20 buses. Five displays were also visible on Metrorail platforms.

Asian-Language Outreach Campaign - EPA continuously seeks to make information about pesticide safety available to non-English speaking members of the U.S. population. In FY 2005, the Pesticide Program continued work to translate several pesticide safety publications into Chinese, Korean, and Vietnamese. Various other publications that have been translated into Chinese, including booklets on IPM and safe control of cockroaches and rodents, continued to be widely distributed.

Promoting Responsible Pest Management Practices in Schools and Homes

IPM in Schools Initiative - Through the [IPM in Schools Initiative](#), EPA encourages schools to adopt IPM practices to reduce children's exposure to pesticides. In FY 2005, EPA helped initiate IPM programs in

Salt Lake City, UT, and several Florida schools districts. In partnership with the U.S. Army and the IPM Institute of North America, EPA also assisted in opening the first IPM Star certified child development center for the U.S. Army. National IPM experts and EPA also joined efforts to build a new database tool to help school districts establish and manage comprehensive school facility self-assessment programs. The database, which will be showcased in the 2006 National IPM Symposium in St. Louis, provides schools with guidance on how to initiate, sustain, and measure their school IPM programs. The draft Healthy School Environments Assessment Tool (HealthySEAT) and more information are available at <http://www.epa.gov/schools/>.

Promoting IPM in Public and Affordable Housing - In FY 2005, EPA worked with the National Center for Healthy Housing and the Department of Housing and Urban Development (HUD) to promote the adoption of IPM approaches to pest control in low-income housing. The National Center for Healthy Housing provides training to housing inspectors, property managers, and public health officials on techniques to minimize environmental hazards in the home, from mold and pests to the misuse of pesticides. The Pesticide Program provided comments to the Center on the IPM portion of its training, as well as IPM contract specifications and technical guidance, outreach materials, and a short article for publication in its quarterly update to the public housing community. The Program also made use of the training curriculum as a way to raise awareness of pesticide outreach materials, which as a result, have become more widely solicited by the housing community.

Lawns and the Environment Initiative - EPA's Pesticide Program continues to play an active role in the Lawns and the Environment Initiative, a voluntary effort aimed at encouraging environmentally responsible lawn and landscaping practices on over 50 million acres of turf and lawn in the United States. A 2004 national conference led to the development and ratification of a set of guidelines for sustainable landscaping practices. Additionally, two pilot projects were initiated by EPA's mid-Atlantic regional office in Bucks County, PA, and by the San Antonio (TX) Water System. In FY 2005, these projects continued monitoring for environmental results in response to public education. EPA expects the initiative to be completed in early FY 2006 with a Proclamation of Environmental Guiding Principles, which will provide a common outreach framework and guiding philosophy.

Training and Educating Workers

A Safe Working Place for the Honduras Field Worker - In FY 2005, the Pesticide Program partnered with the National Association of State Departments of Agriculture, Crop Life Latin America, and Crop Life Honduras to protect human health and the environment through the establishment of a sustainable program to train Honduran farmers and workers on the safe and proper use of pesticides. A committee of Honduran stakeholders, including government, academia, industry, exporters, regional and international organizations, non-governmental organizations, and Peace Corps developed a mission statement, strategic plan, budget, and timeline. Many stakeholders also pledged in-kind contributions, such as use of training sites, personnel, and materials. A number of training sessions were held in FY 2005, reaching a substantial number of trainers, farmers, and field workers.

The North American Pesticide Applicator Certification and Safety Education Workshop - The Pesticide Program, working with state pesticide agencies, state extension services, safety experts, and other stakeholders, organized this biennial meeting that gives EPA's partners the opportunity to discuss a variety of issues including innovative educational and regulatory tools and projects, new compliance issues, resource sharing, training methods, international cooperative projects, and the needs, trends, and successes in applicator safety education. The meeting had various presentations focusing on increasing levels of safety, competency, and security for pesticide applicators and workers. Additional information can be found at <http://ipcm.wisc.edu/workshop2005/>.

EPA's Pesticide Worker Safety Program - The Pesticide Program issued the final report on its national assessment of EPA's Pesticide Worker Safety Program. This large, multi-year undertaking included a

comprehensive assessment of the field implementation of both the agricultural worker protection regulation and the pesticide applicator certification regulation. The results of the effort, available in the [National Assessment Report](#), helped the Program to identify key activities that will improve its pesticide worker safety program in areas such as expanding and upgrading worker training, assuring competency of pesticide applicators, improving program coordination and communication with our partners, promoting safer work practices, training health care providers, monitoring pesticide incidents, and focusing on better field inspection and enforcement efforts.

Pesticide Safety Education Program - The Pesticide Safety Education Program (PSEP) supports efforts to train and certify pesticide applicators in using restricted-use pesticides. In FY 2005, EPA's Pesticide Program worked with USDA and a group of experts to conduct a comprehensive assessment of PSEP and provide a [Strategic Program Assessment Report](#). The report evaluates the current ability of PSEP to support national goals to achieve safe use of pesticides, as well as to use information to affect future program directions. This effort assisted EPA in identifying areas for future improvement, such as improving the program's funding mechanism, setting training priorities, and expanding the scope of pesticide applicator certification regulations.

Pesticide Applicator National Core Exam and Manual - The core exam project, sponsored by EPA's Pesticide Program and Canada's Pest Management Regulatory Agency, is a valid tool to measure the minimum competency of new pesticide applicator candidates on basic or "core" principles common to all applicators. The exam is the result of an effort by a committee of pesticide applicators, pesticide safety educators, and state, provincial, and federal representatives from the United States and Canada. Successful completion of the exam is an important competency screen for applicators to become certified to purchase, use, and supervise the use of restricted use pesticides. The companion core manual prepares individuals to take the core exam. Additional information about the [certification and training of pesticide applicators](#) is available on EPA's Web site.

Worker Protection Standard How-to-Comply Manual - In FY 2005, EPA updated the agricultural worker protection regulation's [How-to-Comply Manual](#). This compliance assistance tool was updated to reflect revisions to a regulation designed to reduce the risk of pesticide poisonings and injuries to agricultural workers. An EPA and state member workgroup compiled the new edition. The agricultural worker protection regulation protects workers on farms, forests, nurseries and in greenhouses. It contains requirements for pesticide safety training, notification of pesticide applications, and use of personal protective equipment, restricted entry intervals following pesticide application, decontamination supplies, and emergency medical assistance. This compliance manual will facilitate better protection of workers from the potential risks from pesticides.

Pesticide Partnerships and Grants

Through the establishment of partnership programs and the awarding of grants, EPA's Pesticide Program is working in a number of arenas to help encourage both responsible and innovative pesticide management practices. In FY 2005, the Program continued to forge cooperative agreements with partners from state and federal government agencies, tribes, universities, private organizations and institutions, pesticide users, and public interest groups to promote activities that further reduce the risks posed by pesticides.

Promoting Stewardship and Risk Reduction

Strategic Agricultural Initiative (SAI) - The [SAI](#) Program reduces human and environmental risks in food production systems by helping farmers transition to more sustainable farming approaches. The program has one agricultural specialist in each of EPA's ten regions who help ensure the safety and sustainability of American agriculture. Established in 1998 by EPA's Office of Pesticide Programs, the SAI team works with farmers, researchers, and other environmental agencies to implement reduced risk pest management strategies. As illustrated in the recently created [SAI Database](#), SAI program staff helped producers implement reduced risk pest management strategies on over 780,000 acres of farmland nationwide in the past two years. This led to a reduction of at least 30 percent in the use of highly toxic pesticides on those acres. In the next five years, similar reduced risk pest management strategies could impact nearly 4 million acres of farmland and continue to improve the safety and sustainability of American agriculture. With its innovative web-based tools and national commitment to helping farmers adjust to federal pesticide regulations, the SAI Program will continue to use innovative methods to turn federal investment into significant, measurable results.

Pesticide Environmental Stewardship Program (PESP) - [PESP](#) is a voluntary partnership program with over 170 members committed to reducing the potential risks associated with pesticide use. In FY 2005, over 80 members submitted pesticide risk-reduction strategies for hundreds of activities, including technical assistance, training, outreach, research, efficacy demonstrations, and benefit evaluations. In July 2005, over 140 PESP members, EPA liaisons, and other stakeholders participated in a PESP National Meeting with the theme, "Working Together Toward Common Goals." During the meeting, 16 members were recognized as 2005 PESP Champions for their efforts in preventing pollution and reducing pesticide risk.

Biopesticide Demonstration Grants - In FY 2004, EPA entered into an Interagency Agreement with USDA's [IR-4 Program](#) to establish the [Biopesticide Demonstration Grant Program](#). IR-4 works with growers, scientists, and commodity organizations to identify minor crop pest control needs. In FY 2005, EPA collaborated with IR-4 to fund 16 grants designed to demonstrate and promote the effective use of registered biopesticides within agricultural Integrated Pest Management (IPM) systems. Biopesticides are used in conjunction with conventional pesticides as a risk-reduction measure or are combined with other biopesticides within biologically intensive IPM systems to improve efficacy. Crops involved in the demonstrations funded in 2005 include apple, blueberry, peach, lettuce, cucurbits, beans, winegrapes, broccoli, turf, ginseng, tomato, and stored potato.

Supporting Regional and Tribal Projects

PESP Regional Grants - Under the Federal Insecticide, Fungicide, and Rodenticide Act, the Pesticide Program and EPA's regional offices make grants to states and federally recognized Native American Tribes. The [PESP Regional Grants](#) have been supported with State and Tribal Assistance Grants (STAG) funds since 1996. Reflecting the broad mission of PESP, these grants support research, public education,

training, monitoring, demonstrations, and studies that advance pesticide risk reduction. In FY 2004, approximately \$500,000 supported 13 projects through this program. In FY 2005, similar funding will support 10 projects, with 1 being conducted in each region. These projects complement continuing risk-reduction efforts and PESP activities in EPA's 10 regions.

Annual Tribal Special Project Grants - The Pesticide Program completed its review of 22 tribal grant proposals received in FY 2005 under its annual competitive grant solicitation. The program was able to provide full funding for 10 tribal proposals and partially fund an 11th. The proposals received from the regions covered a wide spectrum of tribal pesticide issues including IPM, water quality, pesticide program development, invasive species, and a variety of education and outreach initiatives focused on protecting health and the environment in Indian country. The current process is being evaluated by an objective outside contractor, and lessons from the historical evaluation this year will help the Program improve future decision making and streamline the submission and review process. Descriptions of grants awarded under this program are available on the [Tribal Pesticide Program](#) Web site.

Increasing Pesticide and Worker Safety

NIOSH SENSOR Inter-Agency Agreement - In FY 2005, EPA renewed an agreement with the National Institute of Occupational Safety and Health (NIOSH) to expand the Sentinel Event Notification System for Occupational Risk (SENSOR) program. The new agreement will increase the number of states in the SENSOR-Pesticides program and expand occupational illness and injury surveillance capacity within state health departments in areas of the country with sizeable agricultural worker populations. NIOSH will provide funding and technical support to state health departments to conduct surveillance and followup on reports of occupational pesticide poisonings.

Association of Farmworker Opportunity Programs (AFOP) Cooperative Agreement - EPA has had a long history of cooperation with AFOP AmeriCorps members in carrying out education programs to reduce the risks of pesticides. In FY 2005, EPA signed a new agreement with the AFOP, under which EPA plans to provide \$2 million over the course of five years for the purpose of establishing programs at 22 sites in 13 states working with AmeriCorps members to educate farmworkers in rural areas about worker protection measures and safe pesticide practices.

Pesticides and National Strategies for Health Care Providers - EPA's Pesticide Program granted two cooperative agreements to continue the [national initiative to improve the training of health care providers](#) in the recognition, diagnosis, treatment, and prevention of pesticide poisoning among those who work with pesticides. The University of Washington Pacific-Northwest Agricultural Safety and Health Center will work with decision makers and faculty at academic institutions and professional associations or organizations to create institutional change in educational settings, and the Migrant Clinicians Network will work directly with health care providers to change the practice of primary care so that pesticide-related health conditions are recognized, effectively managed, and prevented in practice settings.

National Association of State Departments of Agriculture (NASDA) Research Foundation - EPA awarded a cooperative agreement to the NASDA Research Foundation to develop and improve programs on pesticide safety both nationally and internationally. The project will analyze the current status of private and public programs on pesticide safety education and training, conduct outreach meetings with experts and stakeholders from the agricultural community to assess needs, and make recommendations for improved programs and materials for agricultural workers, pesticide applicators, health providers, growers, and regulatory agencies.

Reducing Pesticide Spray Drift

Spray Drift Reduction Technology Project Awarded Grant - In FY 2005, EPA's Office of Research and Development (ORD) awarded a \$290,000 grant to an EPA team composed of staff from the Pesticide Program, ORD, and EPA's Pacific Southwest regional office to continue its work on the pesticide Drift Reduction Technology project. This project addresses significant environmental risk issues with innovative technology and partnerships with other governmental agencies and the private sector. The grant is to be used to design and implement a verification test method for pesticide application technologies that hold promise for significant spray drift reduction. The ultimate goal of the project is to achieve risk reduction by promoting sales and use of lower-drift application equipment. Applicators that use verified drift-reducing technologies could benefit from incentives such as fewer label restrictions on applications, greater flexibility in how to make applications, more acceptable application days, and potentially lower insurance premiums.

National Agricultural Aviation Research & Education Foundation (NAAREF) Cooperative Agreement - Under this agreement, NAAREF will work to help reduce pesticide spray drift incidents through the development of education programs for aerial applicators that will provide information on the latest technology to reduce pesticide drift. NAAREF is also working with the National Agricultural Aviation Association, the Professional Aerial Applicators Support System, state departments of agriculture, and the American Association of Pesticide Control Officials to present a comprehensive drift reduction educational program at annual, regional, and state meetings, in order to reach a minimum of 1,500 aerial applicators annually.

Reregistration and Tolerance Reassessment

As part of its efforts to ensure that all pesticides meet current health and environmental standards and product labeling requirements, EPA's Pesticide Program is reevaluating older pesticides and determining whether or not they are eligible for reregistration. EPA is also reassessing tolerances (limits on pesticide residues in food) to ensure that they meet the safety standard established by the [Food Quality Protection Act \(FQPA\)](#) of 1996. In conducting these assessments, EPA relies on the best available scientific data, as well as extensive input from the public and other stakeholders.

In FY 2005, EPA completed 27 Reregistration Eligibility Decisions (REDs) for a total of 271 completed and 231 canceled cases. EPA also completed 13 Tolerance Reassessment Decisions (TREDs) and reassessed 722 tolerances. 7,817 tolerance reassessments have been completed, and EPA expects that almost all of the 9,721 tolerances will be reassessed by the August 2006 FQPA deadline. Of the 1,904 tolerances remaining, 528 have been individually assessed through Interim Reregistration Eligibility Decisions (IREDs) but will also be considered in a cumulative assessment before the reassessment is considered complete.

The Pesticide Program is committed to completing REDs for all food-use pesticides and all tolerance reassessment decisions by August 2006, and completing REDs for the remaining reregistration pesticides by October 2008. EPA has placed considerable emphasis on ensuring that resources are in place and schedules are clearly tracked toward meeting these goals.

Risk Assessment Highlights

Soil Fumigant Assessments - Soil fumigants are pesticides that, when applied to soil, form a gas to control pests that live in the soil and disrupt plant growth and crop production. Used on a wide range of crops, soil fumigants play an important role in agriculture, but also have the potential to pose safety concerns. In FY 2005, EPA announced that it is assessing risks and will develop risk management decisions for five soil fumigant pesticides (chloropicrin, dazomet, metam sodium, methyl bromide, and a new active ingredient, iodomethane). EPA's goal in assessing the soil fumigants is to ensure the safety of human health and the environment while also maintaining benefits to agriculture. The soil fumigants are being assessed concurrently to ensure that risk assessment approaches are consistent and to make informed risk management decisions based on a level playing field, considering how mitigation for one fumigant may affect the risks and benefits of the others. Preliminary risk assessments for four soil fumigants (dazomet, metam sodium, methyl bromide, and Telone) were issued in 2005. Additional information on [fumigants](#) is available on EPA's Web site.

N-methyl Carbamate Cumulative Risk Assessment - The [N-methyl carbamate pesticides](#) affect the nervous system by reducing the ability of enzymes to transfer nerve impulses from cell to cell and overstimulating nerves and muscles, causing symptoms such as weakness or paralysis of muscles. In August 2005, the Pesticide Program released its [preliminary cumulative risk assessment for the N-methyl carbamates](#). This assessment is based on evaluation of the potential for people to be exposed to more than one member of this group of pesticides at a time and considers exposures from food, drinking water, and residential sources. The Program submitted the assessment to the Scientific Advisory Panel (SAP) for review and will consider its recommendations, as well as comments and additional data from the public, in revising the preliminary assessment. Once completed, the revised assessment will assist the Agency in evaluating and managing the cumulative effects of the N-methyl carbamates. Additional information about [cumulative risk](#) is available on EPA's Web site.

Reregistration Eligibility Decisions and Tolerance Reassessment Highlights

2,4-D RED - 2,4-D is a widely used herbicide in agriculture, pasture and rangeland, and on residential lawns. In FY 2005, the Pesticide Program completed its RED for 2,4-D, which determined that 2,4-D is eligible for reregistration as long as registrants take certain specified measures to reduce potential risks posed by its use. Mitigation measures include reducing application rates for turf and residential lawns; providing more detailed, use-specific label directions and application restrictions for the direct aquatic use of 2,4-D to control aquatic weeds; and prohibiting fine sprays to prevent potential spray drift risks to wildlife and nontarget plants. The registrants also must provide information on the proximity of federally listed endangered species to 2,4-D use sites. This information will be used by the Agency's Endangered Species Protection Program to develop recommendations to avoid potential adverse effects to listed species. The [2,4-D RED](#) and [additional information](#) are available on EPA's Web site.

EBDC REDs - The EBDCs are broad-spectrum fungicides used on agricultural crops, ornamentals, and turf. In FY 2005, EPA completed REDs and reassessed tolerances for the three EBDCs—mancozeb, maneb, and metiram—which considered exposure from all sources of a common degradate, ethylene thiourea. EPA decided that all uses of the EBDCs supported by registrants are eligible for reregistration, provided that registrants implement risk mitigation measures described in the REDs (as summarized below) and make required changes to product labels. Additional information and the REDs for [mancozeb](#), [maneb](#), and [metiram](#) are available on the CD-ROM and EPA's Web site.

Mancozeb - Mitigation measures include use restrictions such as limiting the number of applications allowed to cut flowers per year and requiring a pre-harvest interval for sod farm turf. Personal protective equipment (PPE) and engineering controls are required—for example, water soluble packaging for wettable powder formulations used on turf, and respirators for the remaining uses of the wettable powder formulation. In addition, foliar use on cotton, pineapple propagation use, and uses on residential lawns, athletic fields, and pachysandra are to be canceled.

Maneb - Mitigation measures include canceling use on crops such as sweet corn, apples, grapes, Kadota figs, peanuts, and seed treatment to rice; reducing the application rate on turf; and prohibiting the use of wettable powder formulation products for aerial and chemigation applications. Additional PPE is required for some mixer/loader and/or applicator scenarios. Engineering controls are required, including dust collection equipment for commercial potato seed-piece treatment and enclosed cockpits for aerial applications.

Metiram - Metiram is used only on apples, potatoes, and leatherleaf ferns. Mitigation measures include use restrictions such as limiting the number of applications allowed to leatherleaf ferns per week/year, reducing the pre-bloom maximum application rate, and reducing the maximum number of applications for apples and potatoes. Additional PPE is required for some worker scenarios.

Chlorsulfuron RED - Chlorsulfuron is one of the few sulfonyl urea herbicides to undergo reregistration. Most herbicides in this class were initially registered after 1984 and are not subject to reregistration but EPA expects to address them as a group early in registration review. In FY 2005, EPA stipulated that, to be eligible for reregistration, chlorsulfuron registrants must implement spray drift reduction measures through label changes. Additional information about [chlorsulfuron](#) is available on the EPA's Web site.

Antimicrobial Reassessments - In accordance with statutory requirements, antimicrobial formulations for sanitizing or disinfecting food-contact surfaces other than food packaging, previously regulated by the Food and Drug Administration, are to be regulated by EPA. Therefore, EPA is responsible for

reassessing tolerances for over 60 pesticides by FY 2006, 35 of which were completed in FY 2005. To accomplish this goal, EPA has categorized and grouped the pesticides according to chemical characteristics and developed a schedule for completing the reassessments on time.

Cancellations and Phaseout Highlights

Chlorpyrifos Pre-Construction Termiticide Exit Strategy - Chlorpyrifos is an organophosphate insecticide. In August 2005, the Pesticide Program provided a notice to distributors, retailers, and pest control operators, detailing an exit strategy for chlorpyrifos products that are labeled for the pre-construction termiticide use. The notice reminds the user community that as of December 31, 2005, chlorpyrifos products may no longer be sold, used, or distributed for pre-construction termite control. It also includes details on how relabeling and/or stickering the products for other lawful uses already on the label can be accomplished in order to deplete any existing stocks. The notice is intended to prevent improper disposal of unsold or unused products, as well as to reduce the enforcement burden on states. The Chlorpyrifos IRED was completed in September 2001. Additional information on [chlorpyrifos](#) is available on EPA's Web page.

Azinphos-methyl (AZM) Cancellations - The IRED for AZM, an organophosphate insecticide, was completed in 2001, and included a determination that AZM uses should be canceled, phased out, or in some instances, allowed to continue under time-limited registrations. In accordance with an AZM Memorandum of Agreement (MOA) signed in 2002, Group 2 uses of AZM (cotton, cranberries, peaches/nectarines, potatoes, southern pine seed orchards, and caneberries) were scheduled to be phased out by December 31, 2005. However, based on comments received in response to a *Federal Register* notice announcing requests from AZM registrants to remove the AZM uses from their manufacturing-use product labels, EPA decided to extend the last date for Group 2 uses to September 30, 2006. EPA proposed this date to avoid difficulties and confusion to growers that could result from a mid-use-season stop use date. Additional information on [AZM](#) is available on EPA's Web site.

Thiram Use Cancellation - The Thiram RED was completed in September 2004. In order to reduce dietary risks posed by the chemical, the registrant requested voluntary cancellation of thiram uses on apples. After publishing a notice of receipt of request for voluntary cancellation in the Federal Register and receiving no comments during the public comment period, EPA issued the final cancellation order terminating the apple use of thiram in late FY 2005. Additional information on [thiram](#) is available on EPA's Web site.

Policy and Regulatory Improvements

EPA's Pesticide Program continually works to update and improve its policy and regulatory framework through additions and revisions to the rules and procedures that govern activities such as review of new and existing registrations, programs with state and federal co-regulators, and oversight of user-level programs. In FY 2005, the Program continued to advance regulatory processes that maximize its use of the best available science and information technology, enhancing its capacity to make high-quality decisions, increase productivity, incorporate stakeholder participation, and effectively and efficiently carry out its duties of protecting public health and the environment.

Program Improvements

PRIA Process Improvements - The [Pesticide Registration Improvement Act \(PRIA\)](#), effective in March 2004, required EPA to make determinations on pesticide applications within specified review times, and also initiated a system under which EPA charges fees for many applications received for pesticide registrations. In FY 2005, the Pesticide Program continued to make significant improvements in the pesticide registration process, including revision of internal procedures to ensure that fee waiver decisions are always made within the 60-day review period, resulting in an average time of 21 days to determine if a fee waiver should be granted. Two public meetings of the Pesticide Program Dialogue Committee PRIA process improvement workgroup were held in FY 2005, in which EPA described and received suggestions from stakeholders on improving its internal processes to enable shorter FY 2006 PRIA timeframes. The first [PRIA Annual Report](#) details information about the Pesticide Registration process and ways in which EPA has improved the process. The Program also formed a Labeling Committee to resolve generic policy issues concerning labels and, under this committee, established a Label Review Team to update and maintain currency of the [Label Review Manual](#).

Registration Review - In anticipation of completing the reregistration and tolerance reassessment program, EPA is developing the Registration Review program, mandated by the Food Quality Protection Act. Under this program, all pesticides will be reviewed every 15 years to ensure that they meet current health and safety standards. In July 2005, EPA issued a proposed Procedural Regulation for Registration Review and provided a 90-day public comment period. During the design of the new program and development of the proposed Procedural Regulations, EPA also actively engaged a diverse group of stakeholders, the Pesticide Program Dialogue Committee, and its Registration Review Workgroup, for input and advice. Additional information about the [Registration Review Program](#) is available on EPA's Web site.

Endangered Species Protection Program - In FY 2005, the Pesticide Program worked to finalize its approach to field implementation of the Agency's [Endangered Species Protection Program \(ESPP\)](#). The goal of the ESPP is to carry out responsibilities under the Federal Insecticide, Fungicide, and Rodenticide Act in compliance with the Endangered Species Act by providing appropriate protection to listed species and their designated critical habitats from potential harm due to pesticide use, while at the same time not placing unnecessary burden on the agriculture community and other pesticide users. EPA will implement its program through pesticide label statements referring users to Endangered Species Protection Bulletins, as appropriate, that will contain geographically specific pesticide use limitations, when such limitations are necessary to protect federally listed species or their designated critical habitat from potential harm due to pesticide use.

Emergency Exemptions

Section 18 Rule - In recent years, the Pesticide Program has been working with states to revise the regulations that allow state and other federal agencies to request emergency exemptions for unregistered uses of registered pesticides to address emergency pest conditions for a limited time. The rulemaking is primarily for the purpose of streamlining and improving the application and review process for emergency exemptions. These revisions are intended to reduce the burden to both applicants and EPA, allow for quicker emergency response by the Agency, and provide for consistent and equitable determinations of "significant economic loss" as the basis for an emergency. These revisions should not compromise protections for human health and the environment or significantly affect current approval rates for exemption requests. The final rule is scheduled to publish early in FY 2006. Additional information about [Section 18](#) is available on EPA's Web site.

Tribal Consultations on Sections 18 and 24(c) - In FY 2005, EPA's Pesticide Program continued efforts to serve the needs of tribal stakeholders, initiating consultation calls to discuss findings that will allow for limited availability of Section 18 and 24(c) label uses within tribal borders. The Program is developing a novel approach that allow growers in Indian country to use the same pesticides for combating pests in emergency situations as growers in neighboring counties. Under federal law, tribes and farmers in Indian country do not explicitly have access to the benefits of pesticide emergency exemptions (Section 18) or special local needs registrations (Section 24(c)). These exceptions to full registration are especially useful when growers in a particular region identify a problem that currently registered pesticides will not alleviate, such as the arrival of a new pest species from abroad. This gap in national protection could allow pest infestations to go unchecked in Indian country, with the potential to devastate crops in Indian country and beyond. The pilots, if approved, will expire in December 2007, and EPA will assess whether or not this approach should be continued, discontinued, or expanded.

Storage, Disposal, and Labeling

Container and Containment Rule - The Pesticide Program continued work to develop regulations governing the design and integrity of pesticide containers and containment facilities. This rulemaking serves to minimize human exposure during container handling, facilitate container disposal and recycling, increase the use of refillable containers, improve disposal instructions on pesticide labels, and reduce environmental contamination at facilities where large pesticide tanks are stored. As part of the process, the Program solicited, received, and considered comments from the public by reopening the public comment period for 75 days in 2004. Additional information about the [Container and Containment Rule](#) is available on EPA's Web site.

Better Labels for Mosquito Control Products - EPA issued a [Pesticide Registration Notice](#) with seven new recommendations to pesticide registrants and others to improve the consistency and clarity of label statements for pesticide products used to control adult mosquitoes. These improvements, as they are adopted on product labels, will help public health mosquito control officials use the most effective techniques while ensuring that use of these products will not pose unreasonable risks to public health or the environment. EPA worked with state agencies to develop initial recommendations and presented them at two public meetings of the Pesticide Program Dialogue Committee, an advisory committee to EPA representing a full spectrum of interests, including pesticide manufacturers, public health agencies, academia, user groups and public interest groups. [Additional information about the new recommendations](#) is available on EPA's Web site.

Data and Study Requirements

Proposed Human Studies Rule - In September 2005, EPA proposed a rule that will establish stringent enforceable ethical safeguards governing the conduct of third-party intentional dosing research with human subjects. Among other new ethical protections, EPA proposed to prohibit all new third-party intentional dosing research with children and pregnant women intended for submission to EPA under the pesticide laws, and a categorical ban on EPA's conduct or support of any intentional dosing studies that involve pregnant women or children, with pesticides or any other substance. This rule is intended to ensure that people who volunteer for third-party pesticide studies involving exposure to humans are treated ethically, with full disclosure of potential risks, and to strongly discourage and prevent the conduct of human studies that do not meet high ethical and scientific standards. As part of its efforts to involve the public and create transparency in the public decision making process, EPA also solicited stakeholder input and comments through a public comment period and held a public meeting to brief stakeholders. Additional information about the [protection of human test subjects](#) is available on EPA's Web site.

OECD Templates for Study Summaries - The Pesticide Program, in collaboration with EPA's Office of Pollution Prevention and Toxics, Canada's Pesticide Management Regulatory Agency, and a team of major North American registrants, assisted in the development of a new set of templates that the chemical industry can use to prepare summaries of new studies for submission to the Pesticide Program. This initiative has been facilitated at the global level by the Organization for Economic Cooperation and Development (OECD) for regulatory agencies of all member countries. The effort in FY 2005 resulted in 85 unique electronic templates for corresponding study requirements across all scientific disciplines. In FY 2006, the Pesticide Program and other organizations mentioned above will focus on information technology development to enable receipt and use of submitted study summary templates. When OECD templates become operational (on a voluntary basis), the Pesticide Program believes this will lead to greater consistency in study reports, efficiency for industry and EPA, facilitation of international worksharing, and quicker decisions.

Part 158 Data Requirements for Registered Pesticides - Because scientific understanding and concerns related to the potential risks of pesticides have evolved, the Pesticide Program has in recent years been working to update the data requirements specified in 40 CFR Part 158, which date back to 1984. The revised rules will further EPA's ability to strike an appropriate balance between the need for adequate data to make informed risk management decisions and the burden of data collection, and will also ensure that pesticide registrations meet federal standards designed to protect public health and the environment.

Conventional Pesticides - In March 2005, the Agency published a proposed rule on data requirements for conventional pesticides. As part of this process, the Program solicited, received, and considered public comments through an extended, 180-day public comment period and also hosted a technical workshop. The proposed rule codifies data requirements that have been imposed on a case-by-case basis, revises some existing data requirements, adds some new studies, reformats the requirements, and revises general procedures and policies associated with data submission for pesticides. This rule is scheduled to be finalized by FY 2007.

Biochemical and Microbial Pesticides - The Agency has under development a proposed rule for Biochemical and Microbial Pesticides. As in the case of conventional pesticides, the proposed rule is intended to codify data requirements that have been imposed on a case-by-case basis, revise existing data requirements, and add new studies.

Registration Activities

EPA's Pesticide Program is entrusted with the responsibility of evaluating and registering pesticides so that effective means for pest control are available. The Program must ensure that these pesticides meet stringent federal standards designed to protect public health and the environment.

The registration program works to coordinate its activities with EPA's pesticide reregistration and tolerance reassessment activities, as well as with other voluntary stewardship and risk-reduction programs, to make new pesticides and alternatives available as older pesticides are phased out. Through its expedited registration process for reduced-risk chemicals, the registration program promotes the availability and use of safer pest control products, placing priority on registering pesticides that may be used as alternatives to organophosphates (OPs) and methyl bromide (MBr).

In FY 2005, EPA registered 22 new active ingredients, of which 2 are [antimicrobials](#), 12 are [biopesticides](#), and 8 are [conventional](#) pesticides. Two of the eight conventional pesticides have associated reduced-risk uses. EPA also registered 164 new food uses for previously registered active ingredients, of which 27 are reduced risk, 45 are OP alternatives, and 11 are MBr alternatives.

Antimicrobial Highlights

Silver Chloride - Silver chloride is an antimicrobial disinfectant intended for use in residential, in-ground and above-ground swimming pools from 20,000-40,000 gallons. The product does not disinfect by itself but must be used as a co-biocide with any EPA-registered chlorine swimming pool product.

Tetraacetylenediamine (TAED) - TAED is a new active ingredient precursor that, when mixed with a peroxide source, produces peracetic acid. TAED is a novel chemistry that allows for simple, on-site generation of peracetic acid for use as an antimicrobial agent. This eliminates the need to stabilize and transport peracetic acid, which is not stable over time.

New Use for Reducing Biofilm in Dental Unit Water Lines - This is a two-part system for reducing biofilm in dental unit water lines that are connected to air/water syringes and drill pieces. One product containing 1.05 percent hydrogen peroxide is mixed with the companion product containing quaternary ammonia compounds, and the combination is introduced into the lines for overnight treatment. The two products must always be used together. This is the first dental unit water line product with a claim for more than just odor control, and it is supported by field efficacy studies.

New Use for Ethylene Oxide (ETO) - This is a new use for disinfecting musical instruments. ETO is registered to kill pathogens that may be in the mouthpiece of instruments, which could potentially spread to children and others who rent or use the instruments. This registration also provides a new tool to help reduce the spread of various pathogens that may occur when workers from various countries test the mouthpieces of musical instruments before shipment. Retailers, school music departments, and others can now disinfect instruments before sale and use.

New Use for Sodium Chlorite/Sodium Dichloro Isocyanurate Dihydrate - This is a new use for preventing slime growth and microbial contamination in potable drinking water stored or present in drinking water coolers. This new use will add to the arsenal of products available for addressing drinking water concerns in the aftermath of Hurricanes Katrina and Rita.

Biopesticide Highlights

[Cry34/35](#) - Cry 34/35 is a new corn plant-incorporated protectant (PIP) in Event DAS-59122-7 Corn, derived from *Bacillus thuringiensis* (Bt) proteins Cry34Ab1 and Cry35Ab1. This is the second PIP to offer protection against corn rootworm, and is expected to result in a further reduction of chemical insecticide use by growers.

[Alternaria destruens strain 059](#) - *Alternaria destruens* strain 059 is a fungal herbicide intended for control of dodder. A naturally occurring microorganism, it is to be used as an herbicidal agent in agricultural fields, dry bogs, and ornamental nurseries. This product is of particular importance to the cranberry industry, which is in need of new dodder-control mechanisms.

[Paecilomyces lilacinus strain 251](#) - *Paecilomyces lilacinus* strain 251 is a naturally occurring soil fungus for control of nematodes. Although many species of *Paecilomyces* release potent toxins, no such toxins have been detected in this strain. The product is applied to the root zone of crops, where it parasitizes many species of plant root nematodes. It does not harm beneficial nematodes or other tested organisms and is a potential alternative to the more toxic chemicals often used for controlling nematodes.

[Chondrostereum purpureum strain HQ1](#) - *Chondrostereum purpureum* strain HQ1 is a biopesticide for inhibiting sprouting and regrowth in cut stumps of certain deciduous tree species in rights-of-way, wood lots and conifer plantations. An alternative to glyphosate, triclopyr, picloram + 2,4-D, and hexazinone, it provides a biological option where conventional herbicides cannot be used.

[Muscodor albus QST 20799](#) - *Muscodor albus* QST 20799 is a fungus intended for use as a biofumigant alternative for methyl bromide. This strain is expected to control soil-borne, fungal, and bacterial diseases on all food commodities, ornamentals, seeds, and propagules.

For information on all FY 2005 Biopesticide Registrations, please see:

http://www.epa.gov/pesticides/biopesticides/product_lists/new_ai_2005.htm

Conventional Highlights

[Aminopyralid](#) - Aminopyralid is an herbicide associated with reduced-risk uses for control of invasive and noxious weed species in range and pasture land, roadsides, rights-of-way, and industrial vegetation management areas. This herbicide has a more benign toxicology profile than other chemicals registered for these uses (e.g., monosodium methane-arsonate, picloram, dicamba, clopyralid, 2,4-D) and will be applied at a lower rate. Its residual action alleviates the need for repeat applications and will result in a significant reduction in the amount of herbicide applied to the environment for control of noxious weeds.

[Pinoxadin](#) - Pinoxadin is an herbicide associated with reduced-risk uses on wheat (including durum) and barley for postemergent control of grass weeds. Pinoxaden is a potential alternative to several conventional herbicides, such as fenoxaprop-ethyl, difenzoquat-methyl, triallate, and trifluralin. Compared to other chemicals with similar uses, pinoxaden appears to have a favorable risk profile with respect to human health and the environment, and is expected to result in an overall reduction in the amount of herbicides used to control grass weeds in wheat and barley.

[Spirodiclofen](#) - Spirodiclofen is a new active ingredient, part of a new class of chemicals called tetrionic acid insecticides. Tetrionic acids are primarily acaricides (miticides) with insecticidal uses at higher doses and work to inhibit insect development throughout various growth stages. The end-use product is a suspension concentrate with application as a foliar spray (ground only) to the following crop groups: citrus fruit, pome fruit, tree nuts, grapes, and stone fruit.

New Use for Dinotefuran - This is a conditional registration of a pet-use product for controlling fleas on cats. This product, a liquid drop formulation, replaces two spot-on products containing the active ingredient phenothrin. Hartz Mountain Corporation voluntarily agreed to cancel the use of phenothrin on cats and kittens because of toxicity concerns.

New Uses for Sulfuryl Fluoride - These are additional food uses for the fumigant sulfuryl fluoride, for the control of insect pest infestations in food commodities and structures. The use of sulfuryl fluoride was expanded to include additional raw agricultural commodities like coffee beans, cocoa beans, and peanuts, and processed food commodities like powdered milk, dried meat, and rice flour. In addition, sulfuryl fluoride was cleared for use as a space fumigant in food processing and handling facilities. The latter use is considered to be a methyl bromide replacement and is expected to play a key role in methyl bromide critical use exemption application decisions.

Other Registration Highlights

Other Pesticide Ingredient (Inert) Assessments - While inert or “other” ingredients (e.g., solvents or carriers) in a pesticide formulation are not intended to affect target pests, they may nevertheless have hazard potential. Therefore, EPA assesses these ingredients to ensure that their use will not pose unreasonable risks to human health or the environment. In FY 2005, the pesticide registration program created a new branch to handle submissions, reassessments, clearances, and approvals of all inert or “other” pesticide ingredients, resulting in significant improvements in the pace and organization of these efforts. Over the course of the year, EPA also published rules establishing new tolerance exemptions for 17 inert ingredients and reassessed 168 existing tolerance exemptions.

Advancements in Science and Technology

EPA's Pesticide Program relies on the best available science and technology to carry out its mission of protecting public health and the environment, and constantly works to develop and employ new and improved techniques for conducting human health and ecological risk assessments and refining risk assessment processes. In FY 2005, the Program continued to make advancements in science and technology that improve the ability to understand, assess, and ultimately mitigate the potential risks of pesticides to the public and the environment. The Program also maintains a high level of commitment to collaborating with experts in the field and continues to receive and seek input from the [Scientific Advisory Panel \(SAP\)](#) and stakeholders to identify and address areas where methods and procedures could be improved.

Improving Ecological Exposure and Risk Assessment Tools

[Pesticide Fate Database](#) - This new database allows users to search, sort, and retrieve up-to-date pesticide fate and chemistry information that may be used to describe or predict what could happen to a pesticide active ingredient under various conditions when it is released into the environment. The data are derived from studies submitted by pesticide manufacturers in support of the registration/reregistration of pesticide products and include: (1) basic physical and chemical properties, (2) biotic and abiotic degradation half-lives in soil and water, (3) adsorption/desorption constants, (4) bioconcentration factors in fish, and (5) degradates or breakdown products of registered pesticides. For non-agricultural chemicals such as antifoulants and wood preservatives, aqueous availability and leaching data are also included.

[Pesticide Terrestrial Exposure Model](#) - The [T-REX Model](#) automates the calculations needed for estimating pesticide residues on foliage, seeds, and fields, as well as the potential acute and chronic risks to birds and mammals based on these exposures. T-REX has been designed to be easy to use, yet it maintains the level of flexibility needed for the multitude of chemicals and use patterns encountered by risk assessors. Replacing the Agency's previous terrestrial residues and risk calculation tools, this spreadsheet-based model allows the user to calculate dose- and dietary-based risk quotients, loadings, or pesticide per unit area ($LD_{50}ft^{-2}$) for broadcast and banded (liquid and granular) pesticide applications, and seed treatment exposures to birds and mammals. Risk quotients, a prediction of risk, are calculated by dividing the estimated exposure to a pesticide by an effects or toxicity endpoint such as an LC_{50} (the concentration of a chemical where 50 percent of the exposed organisms die). The results are then presented by weight class for various size birds and mammals for each type of pesticide application.

[Golf Course Adjustment Factors for Estimating Aquatic Exposure](#) - Newly developed [golf course adjustment factors](#) reflect the percentage of a golf course that has been treated with an individual pesticide. These factors are used to refine surface water Estimated Drinking Water Concentrations (EDWCs) and Estimated Environmental Concentrations (EECs) generated by aquatic exposure models for golf course turf use scenarios. In the past when an individual pesticide was used on tees and greens, it was assumed in the model scenario that the entire golf course was treated. This assumption can lead to an overestimation of the EDWCs and EECs. The use of an adjustment factor to refine those values can modify this practice by accounting for the percentage of managed land area on a golf course that is not treated with a pesticide.

[Probabilistic Exposure and Risk Model for Fumigants \(PERFUM\)](#) - In FY 2005, after incorporating important recommendations from the [SAP](#), the Pesticide Program began using the [PERFUM Model](#) to estimate exposure distributions around treated fields. PERFUM is based on the Industrial Source Complex—Short-Term, Version 3 model (ISC-ST3), a steady-state Gaussian plume air model. Unlike ISC-ST3, PerfUM incorporates ranges of both field emissions (or flux) and five years of actual

meteorological data. Specifically, for each emission profile considered, PerFUM calculates the downwind concentrations in all directions around the field for every day over a five-year period (for each source of meteorological data considered). From these concentration calculations, the model establishes distances from the field, in all directions, where the concentration declines to a user-defined threshold. Two additional fumigant models—the Fumigant Exposure Modeling System (FEMS) and the Soil Fumigant Exposure Assessment System (SOFEA)—were also reviewed by the SAP. The outputs of the models will provide risk managers significantly more information upon which to base regulatory decisions for this class of chemicals.

NAFTA Guidance for Conducting Terrestrial Field Dissipation Studies - In FY 2005, the Pesticide Program and the Canadian Pest Management Regulatory Agency (PMRA) announced the availability of draft harmonized guidance for conducting terrestrial field dissipation studies. In developing this guidance document, the Program and PMRA conducted an extensive outreach and review program, soliciting input from stakeholders and the technical community through the SAP, three symposia, and a public workshop. Working closely with its stakeholders, EPA and PMRA developed a conceptual model for designing terrestrial studies that will evaluate the overall dissipation of a pesticide in the field. The [draft harmonized guidance and the conceptual model](#) is available on EPA's Web site.

Improving Human Health Exposure and Risk Assessment Tools

Improving Drinking Water and Ground Water Models - As part of the effort to better estimate pesticide concentrations in the public's drinking water supply, the Pesticide Program in FY 2005 worked with the U.S. Department of Agriculture and the U.S. Geological Survey to evaluate the use of currently available leaching models and run-off models in an effort to improve the estimation of pesticide concentrations in ground water and surface water. These efforts have expanded to include not only the mechanistic evaluation of the models, but also the development of spatially explicit and temporally variable methods that can identify potentially vulnerable aquifers and evaluate mitigation options to reduce exposures through drinking water. Such efforts have led to considerable improvements in EPA's ground water estimates. The Program also modified the linked surface water model PRZM-EXAMS to make it more representative of actual field conditions and easier to run. Using PRZM-EXAMS, the Program can estimate the concentration of pesticides in drinking water. Additional information about EPA's [pesticide exposure models](#) can be found on EPA's Web site.

Integrating Drinking Water and Dietary Exposure Estimates - In FY 2005, the Pesticide Program revised its approach to evaluating drinking water exposure so that modeled surface and ground water estimates of drinking water concentration are directly incorporated into the dietary exposure analysis, along with food. This provides a more realistic estimate of exposure because actual reported body weights and water consumption are used instead of the standard values used in the previous approach. The revised approach will allow EPA to more accurately evaluate risks and ensure the safety of the public's drinking water supplies.

Maximum Residue Limit (MRL) Calculation Tool - In FY 2005, the Pesticide Program continued to work with Canada's Pest Management Regulatory Agency (PMRA) as part of a NAFTA workgroup to develop a new tolerance/MRL calculation tool. This tool was completed, reviewed by the NAFTA executive board on several occasions, and first put into formal use by both countries in August 2005. The spreadsheet calculator now serves as a standard that both EPA and PMRA use in establishing their respective maximum residue limits, and will promote tolerance/MRL harmonization and minimize trade restrictions. The [spreadsheet tool](#) and [guidance](#) are available on the PMRA Web site.

The LifeLine Project - The Pesticide Program continued to provide funding to maintain and improve the LifeLine Project, an ongoing effort which utilizes state-of-the-art risk assessment software to capture

unique exposures that may accompany the practice of subsistence lifestyles by tribes. The new software, once populated with tribal data, is expected to improve the Agency's ability to assess risks and empower modeled tribes to perform their own exposure and risk analyses. Additional information about LifeLine is available on the [LifeLine Group](#) Web page.

Improving Models for Exposure and Risk Assessment of Antimicrobial Pesticides – Antimicrobial pesticides, because their use patterns are different from agricultural pesticides, have use and exposure scenarios that standard models were not designed to address. In FY 2005, EPA continued to improve upon several models for assessing exposure and risk for antimicrobials that will expand risk assessment capabilities and result in better protection where necessary:

1. Heating Ventilation and Air Conditioning (HVAC) Model - measures post-application concentration of antimicrobials in residential and commercial HVAC systems to estimate exposure to building occupants;
2. Utility Pole Model - estimates the leaching of pentachlorophenol from utility poles;
3. Antimicrobial Exposure Model - estimates dermal and inhalation exposure to antimicrobial chemicals of workers who handle the chemicals; and
4. Swimmer Exposure Assessment Model ([SWIMODEL](#)) - assesses exposure to more than 200 pesticides registered for swimming pool uses and use in indoor swimming pools and spas.

Methods and Research Development

Microarray Analysis of Hospital Disinfectants - Hospital-acquired infection (HAI) causes enormous casualties and economic damages each year because of the varieties of pathogenic bacteria that have grown resistant to many drugs and antimicrobials. *Staphylococcus aureus*, one of the major causes of HAI, has long been a serious threat to public health because of its numerous toxins and antimicrobial resistance. In FY 2005, the Pesticide Program's Microarray Research Laboratory, in cooperation with the University of Maryland, conducted a study on the response of *Staphylococcus aureus* (upon exposure) to oxidative disinfectants at the genetic level through the use of microarray technology. The results of this study can help identify signature genes that are commonly activated with oxidative disinfectants, which may be used to design new more effective treatments or more efficaciously apply existing compounds. Previous research on the response of *Pseudomonas aureus* (upon exposure) to oxidative disinfectants, including [peracetic acid](#) and [hydrogen peroxide](#), was also published this year.

The Endocrine Disruption Screening Program - The [Endocrine Disruption Screening Program \(EDSP\)](#) is mandated to use validated methods for screening and testing chemicals to identify potential endocrine disruptors, to determine adverse effects and dose-response, to assess risk, and ultimately to manage risk under current laws. Validation of test methods that indicate specific effects of an endocrine disruptor is still underway. In FY 2005, the Pesticide Program corroborated with EPA's Office of Research and Development, Office of Science Coordination and Policy, and Office of Pollution Prevention and Toxics to prepare and implement a research plan for developing *in silico* and *in vitro* methods to prioritize testing for potential endocrine disrupting chemicals, including pesticides. EPA is continuing to investigate these methods for identifying chemicals of interest and regulatory acceptance criteria.

Codex Alimentarius Commission - The Codex Alimentarius Commission is a joint program of the Food and Agriculture Organization (FAO) and World Health Organization (WHO), designed to protect the health of consumers and to ensure fair trade practices in food trade. Codex develops international food safety standards, including pesticide Maximum Residue Limit (MRL) recommendations. In FY 2005, EPA, along with representation from 165 member countries, other international organizations and consumer, environmental, and industry non-governmental groups, continued to contribute technical expertise to the development of these international standards to ensure that they are compatible with U.S.

levels. Many developing countries depend upon Codex MRLs to set acceptable pesticide residue levels in their own countries. More information on Codex is available on the [FAO Codex](#) Web site.

Alternatives to Animal Testing - EPA is working to develop a non-animal assessment approach for evaluating the skin and eye irritation potential and labeling requirements for antimicrobial cleaning product formulations. This initiative, begun in 2004 through a subcommittee of the Pesticide Program Dialogue Committee, made considerable progress in FY 2005. Data from seven companies are being used to develop a background document for review by the Interagency Coordinating Committee on the Validation of Alternative Methods. The paper will provide a testing scheme using alternative methods and the validation support for the scheme. Review ICCVAM expects to complete its review in mid-FY 2006. The Agency would then implement an alternatives policy for these products shortly thereafter.

Retrospective Analyses of Animal Testing Requirements - Under EPA's current toxicology data requirements, an extensive number of laboratory animal toxicity studies must be conducted to support the registration of pesticides. This includes both a 13-week and 1-year dog study. The Pesticide Program recently conducted an extensive analysis of the toxicity results from the dog studies to determine their value in risk assessment. While it was concluded that dogs studies are important for assessing the potential risks of pesticides, it was determined that dog studies of 1-or 2-year duration did not result in appreciably lower hazard values or identify new effects for the majority of chemicals when compared to shorter-duration studies (13 weeks). In May 2005, EPA submitted these [findings](#) to the SAP for review. To support development of a more efficient animal testing paradigm, EPA is also supporting a number of other retrospective analyses of the pesticide database, including the rat reproductive multi-generation tests, rodent cancer bioassay, and the rat neurodevelopmental studies.

FY 2005 New Active Ingredient Registrations	
Total New Active Ingredients Registered*	22
Conventional Chemicals (includes 1 methyl bromide alternative) New uses = 43	6
Conventional Reduced-Risk Chemicals (includes 1 organophosphate alternative) New reduced-risk uses = 7	2
Biopesticides New uses = 1,050	12
Antimicrobials New uses = 2	2

* In FY 2005, new import tolerances were also established for residues of two active ingredients that are not registered in the United States but found on imported food products.

FY 2005 New Uses for Previously Registered Active Ingredients	
Total New Uses (food and nonfood)	338
Total New Food Uses	303
Total New Nonfood Uses	35
New Antimicrobial Nonfood Uses	8
New Antimicrobial Food Uses	0
New Biopesticide Nonfood Uses	7
New Biopesticide Food Uses	132
New Conventional Nonfood Uses	17
New Conventional Food Uses	147
New Conventional Reduced-Risk Nonfood Uses	3
New Conventional Reduced-Risk Food Uses	24

New Methyl Bromide Alternative Uses	11
New OP Alternative Uses	45
Total Tolerances Established for New Uses (for new & existing active ingredients)	510
Total Major Crops Associated with New Uses (for new & existing active ingredients)	175
Total Minor Crops Associated with New Uses (for new & existing active ingredients)	1,825

FY 2005 Section 18 Emergency Exemptions	
Exemption Requests Received	517
Exemptions Granted	340
Exemptions Withdrawn	66
Exemptions Denied	0
Crises Declared	27
Tolerances Established for Section 18s	23
Average Processing Time for Specific, Quarantine, and Public Health Requests	42 days

FY 2005 Reregistration Risk Management Decisions Completed	
REDs	27
Interim REDs and Tolerance Reassessment Decisions	13
Total REDs Completed Through FY 2004	271

FY 2005 Product Reregistration Actions Completed	
Product Reregistration Actions	97
Product Amendment Actions	62
Product Cancellation Actions	342
Total Product Reregistration Actions for FY 2005	501

FY 2005 FQPA Tolerance Reassessment Summary			
Class	Total # of Tolerances to be Reassessed	Total Reassessed Since August 3, 1996	Percent Reassessed
Organophosphates	1,691	1147	67.83
Carbamates	545	317	58.17
Organochlorines	253	253	100.00
Carcinogens	2,008	1530	76.20
High Hazard Inerts	5	5	100.00
Other	5,219	4565	87.47
Total	9,721	7817	80.41

FY 2005 Fast-Track and Nonfast-Track Decisions		
	Fast-Track	Nonfast-Track
Me-Too Product Registrations	340	797
Amendments	2,639	680
Total	2,979	1,477

Special Local Needs Accepted (Section 24(c))

Total for FY 2005 = 745

Experimental Use Permits (EUPs)

Total for FY 2005 = 14

Temporary Tolerances Established for EUPs

Total for FY 2005 = 2